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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,862	06/20/2003	Todd Zankel	30610/39383	8574

7590 01/14/2005

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EXAMINER	
KOLKER, DANIEL E	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 01/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/600,862	ZANKEL ET AL.	
	Examiner	Art Unit	
	Daniel Kolker	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10 - 24* is/are pending in the application.

4a) Of the above claim(s) *11 - 13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *10 and 14 - 24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The amendment filed 16 December 2004 has been entered. Applicant elected Group I, with traverse. The examiner had required restriction between product and process claims. Applicant elected the product claims, and traversed with respect to the restriction between Groups I and V, the product and related process claims, respectively. It is acknowledged that Applicant retains the right to have process claims examined to the extent that they are commensurate in scope with any product claims ultimately found allowable.

Applicant cancelled claims 1 – 9, and withdrew claims 11 – 13. Applicant added new claims 14 – 24. Applicant's remarks dated 16 December 2004 indicate that new claims 14 – 28 had been added, yet the claims that appear on pages 2 – 5 of the same communication end after claim 24. Applicant is requested to clarify whether the final claim is claim number 24 or 28. Claims 10 and 14 – 24 are pending in the current Office Action.

Because the claims are no longer drawn to a single genus, further restriction is required.

Election/Restrictions

Elected Group I. Claims 14 – 24, drawn to compounds comprising Receptor-Associated Protein (RAP) conjugated to enzymes, classified in class 530, subclass 250.

Requirement for Further Restriction Within Elected Group I

Newly presented claims 15 – 17 list multiple patentably distinct compounds. Each compound is a distinct and independent invention, and has a unique structure with unique physical and chemical properties. Searching more than one chemical structure would present a serious burden for the office. Applicant is required to elect a single product from the following list:

a) RAP conjugated to aspartylglucosaminidase
b) RAP conjugated to acid lipase
c) RAP conjugated to cysteine transporter
d) RAP conjugated toLamp-2
e) RAP conjugated to alpha-galactosidase A
f) RAP conjugated to acid ceramidase
g) RAP conjugated to alpha-L-fucosidase

h) RAP conjugated to beta heosaminidase A

i) RAP conjugated to GM2-activator deficiency

j) RAP conjugated to alpha-D-mannosidase

k) RAP conjugated to beta-D-mannosidase

l) RAP conjugated to arylsulfatase A

m) RAP conjugated to saposin B

n) RAP conjugated to neuraminidase

o) RAP conjugated to alpha-N-acetylglucosaminidase phosphotransferase

p) RAP conjugated to phosphotransferase gamm-subunit

q) RAP conjugated to L-iduronidase

r) RAP conjugated to iduronate-2-sulfatase

s) RAP conjugated to heparan-N-sulfatase

t) RAP conjugated to alpha-N-acetylglcosaminidase

u) RAP conjugated to acetylCoA:N-acetyltransferase

v) RAP conjugated to N-acetylglucosamine 6-sulfatase

w) RAP conjugated to galactose 6-sulfatase

x) RAP conjugated to beta-galactosidase

y) RAP conjugated to N-acetylgalactosamine-4-sulfatase

z) RAP conjugated to hyaluronoglucosamindase

aa) RAP conjugated to multiple sulfatases

bb) RAP conjugated to palmitoyl protein thioesterase

cc) RAP conjugated to tripeptidyl peptidase I

dd) RAP conjugated to acid sphingomyelinase

ee) RAP conjugated to cholesterol trafficking

ff) RAP conjugated to cathepsin K

gg) RAP conjugated to alpha galactosidase B

hh) RAP conjugated to sialic acid transporter

ii) RAP conjugated to human alpha-L-iduronidase

jj) RAP conjugated to human alpha glucosidase

Applicant is advised that the above-listed requirement for further restriction is not a species election.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their different classification, recognized divergent subject matter, and/or separate searches, restriction for examination purposes as indicated is proper.

A telephone call was made to Nabeela McMillian on 11 January 2005 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the

process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on (571) 282-0829. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel E. Kolker, Ph.D.

SHARON L. TURNER, PH.D.
PATENT EXAMINER
1-12-05